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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/826,393

Applicant(s)
Florin et al.

Examiner
Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-13 were canceled and new claims 14-33 were submitted [Paper No. 6 filed 6/04/2002].

New claims 14-33 are pending and under examination in the instant office action.

Response to Arguments

Applicants' arguments with respect to the original claims 1-13 have been fully considered but they are not persuasive for the reasons below and they are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

New matter

1. Claims 14-33 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "a primary regenerating tissue but not a somatic embryo" in claim 14 and insertion of the limitation "a primary explant but not a somatic embryo" in the claims 24 and 31 have no support in the as-filed specification. The insertion of this limitation is considered to be a new concept because it does not have a clear literal support in the as-filed specification by way of a generic disclosure or in the specific examples. The generic disclosure appears to indicate the exclusion of a plant material which is "a later developmental stage of the

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plant” (see specification page 2, line 20-24). However, this generic disclosure does not exclude somatic embryo as presently claimed. The specific examples in the as-filed specification demonstrate freezing of “calli” or callus culture (specification page 9, line 7 or page 13, line 31) but the specific examples neither clearly exclude “somatic embryo” neither they clearly demonstrate the intention to exclude “somatic embryo” from the plant material which is subjected to freezing protocols. Therefore, there is no sufficient support for the new genus/concept drawn to exclusion of “somatic embryo”. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation “a primary regenerating tissue but not a somatic embryo” in claim 14 and insertion of the limitation “a primary explant but not a somatic embryo” in the claims 24 and 31 is considered to be the insertion of new matter for the above reasons.

2. Claims 24-30 and 32 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

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Insertion of the limitation “28 g/100 g dwt” in the claims 24 and 32 has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of dehydrating primary explant to a water content of at least “28 g/100 g dwt”. There is no disclosure related to any particular water content in the dehydrated plant material in the as-filed specification. Thus, there is no sufficient support for the new genus drawn to dehydrating primary explant to a water content of at least “28 g/100 g dwt” in the cryopreservation method. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation “28 g/100 g dwt” in the claims 24 and 32 is considered to be the insertion of new matter for the above reasons.

Indefinite

New claims 14-33 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 24 and 31 are indefinite with regard to the phrases “a primary regenerating tissue but not a somatic embryo” and/or “a primary explant but not a somatic embryo”. First, it is

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uncertain as presently claimed and as disclosed in the as-filed specification what plant material is excluded in the method for cryopreservation. Is “zygotic embryo” intended to be excluded too, for example? Second, it is uncertain as claimed what difference is intended, if any, between the claimed “primary regenerating tissue” (claim 14) and “primary explant” (claims 24 and 31).

Further, claims 14, 24 and 31 are indefinite with regard to the phrases “induction medium” and “regeneration medium” in the lack of specific definitions and particularly in view that the claimed media comprise identical sucrose concentrations (see claims 15 and 25). Thus, it appears that no specific differences neither claimed or intended for the media. Therefore, the plant material which is submitted to cryopreservation protocols after being cultured in the claimed media appears to be identical. Yet, the claimed plant material is designated by different phrases wherein the differences are uncertain as claimed.

Claims 27-30 are indefinite and lack antecedent basis for “the plant tissue” in the method of claim 24 which is directed to the use (incubation) of “planting” tissue as claimed.

Thus, the claimed process remains indefinite because it is unclear as claimed what specific active steps are intended and/or what is the plant material or tissue which is intended to be subjected to the process of the cryo-preservation and/or which is intended at the beginning of the whole process.

Claims 24 and 32 are indefinite because it is not particularly clear as claimed what amounts are related to the water contents what amounts are related to weight of plants, what is “dwt” and what is “dwt” for water, for example.

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Art rejection

Applicants are hereby notified that the insertion of new matter into the claims has necessitated the removal of the claim rejection over the references by Hatanaka et al. [IDS-AP], Lecouteux et al. [IDS-AQ] and/or Abdelnour-Esquivel et al. [IDS-AO]. However, removal of new matter will result in the reinstatement of the art rejections under 35 U.S.C. 102(b) and/or under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 14, 16-19, 31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,143,563 [A-7].

Claims are directed to a process for the cryopreservation of plant tissues or primary explant comprising steps of dehydrating, prefreezing and cryofreezing the primary explant wherein the primary explant comprises the tissue that has been subjected to an induction medium or to a regeneration medium for a time sufficient to induce a primary regenerating tissues or primary explant but not a somatic embryo.

US 6,143,563 teaches a process for cryopreservation of plant material or plant callus (see abstract) comprising steps of dehydrating (col. 5, lines 60-63), prefreezing (col. 6, lines 28-39) and cryofreezing (col. 6, line 28) the plant material wherein the plant material comprises the

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tissue that has been subjected to an induction medium or to a regeneration medium for a time sufficient to induce a callus culture but not a somatic embryo (example 3).

The cited patent anticipate the claimed method because it comprises identical active steps and structural elements such as steps of dehydrating, prefreezing and cryofreezing the plant material including callus culture which is “a primary regenerating tissue” or “primary explant” but not a “somatic embryo” as encompassed by the presently claimed invention.

New claims 14-20, 22, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Pence et al. [U] for the reasons as explained in the prior office action and for the reasons below.

Claims are directed to a process for the cryopreservation of plant tissues or primary explant comprising steps of dehydrating, prefreezing and cryofreezing the primary explant wherein the primary explant comprises the tissue that has been subjected to an induction medium or to a regeneration medium for a time sufficient to induce a primary regenerating tissue or primary explant but not a somatic embryo. Some claims are further drawn to the use of plant material derived from *Theobroma cacao*, to the use of incubation media with increasing sucrose concentration or sucrose concentration 0.4 M and 1 M in the process for cryopreservation of plant tissues.

The cited reference is relied upon as explained in the prior office action and repeated herein.

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Pence et al. [U] discloses a process for the cryopreservation of plant tissues or primary explants such as zygotic embryos “but not somatic embryo” derived from *Theobroma cacao* wherein the method comprises steps of preculturing plant material on media with increasing concentration of sucrose from 3% to 21% (abstract or page 145, col. 1, par. 3), dehydrating or slow freezing (abstract or page 144, col. 2, last par.) and cryo-freezing (freeze-drying) the plant material (abstract or page 145, col. 1, line 21). The cited method involves that use of medium with sucrose concentration 1.0 M sucrose (page 145, col. 1, line 4) and about 0.4 M (9% -15%, for example: page 145, col. 1, par. 3). Thus, the cited method appears to anticipate the claimed method because both methods are comprising identical active steps of preculturing, pre-freezing and cryo-freezing the identical plant material such as zygotic embryos “but not somatic embryo” derived from *Theobroma cacao*. Both method encompass the use of substantially similar, if not identical concentration of sucrose in the whole process, particularly in view that the cited reference clearly teaches the use of increasing sucrose concentration at least during pre-culturing step and the use of the medium with 1.0 M sucrose for some of the dehydration/pre-treating/pre-freezing steps.

With regard to the cited reference by Pence et al. [U] (see response page 5, par. 2) applicants’ arguments do not appear to have persuasive grounds because the “advantages” of the present invention which are intended are uncertain a claimed and as argued.

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Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 14-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,143,563 [A-7] taken with Pence et al. [U], US 5,943,821 [B-7] and US 5,922,929 [C-7].

Claims are directed to a process for the cryopreservation of a plant material comprising steps of dehydrating, prefreezing and cryofreezing the plant material wherein the plant material has been subjected to an induction medium or to a regeneration medium for a time sufficient to induce a primary regenerating tissue or primary explant but not somatic embryo. Some claims are further drawn to the use of incubation media with increasing sucrose concentration or sucrose concentration 0.4 M and 1 M in the process for cryopreservation of plant material. Some claims are further drawn to the use of plant material derived from *Theobroma cacao*, *Coffee canephora*, *Coffee arabica* or *Daucus carota*. Some claims are/are further drawn to dehydrating the plant material to 28 g/100 g dwt. Some claims are/are further drawn to the use of prefreezing temperature between -20°C and -40°C.

US 6,143,563 is relied upon as explained above for the disclosure of a process for the cryopreservation of a plant material such as a callus culture. The cited process includes step of treating callus culture with an osmoticum such as sucrose in order to improve viability during freezing (col. 5, lines 44-50) and the cited patent teaches that the choice of osmoticum is depending of a specific type and species of callus culture (col. 6, line 50). The cited method

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allows for cryopreservation of a callus culture derived from any plant species which is capable of forming callus (col. 5, lines 25-31) but it is missing particular disclosure about callus forming capability of plant species such as *Theobroma cacao*, *Coffee canephora* or *Daucus carota*.

However, the cited reference by Pence et al. [U] teaches that plant species such as *Theobroma cacao* is capable to form callus culture (tables 1 and 2, for example). The other references are relied upon to demonstrate that plant species such as *Coffee canephora* is capable to form callus culture (see example 3 of US 5,943,821 [B-7]) that plant species such as *Daucus carota* is capable to form callus culture (see example 1 of US 5,922,929 [C-7]).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the presently claimed method for cryopreservation of plant primary explants or callus culture because the process of plant callus culture is known in the prior art. The prior art teaches that callus of any plant species can be subjected to cryopreservation and the callus cultures derived from the presently claimed plant species including *Theobroma cacao*, *Coffee canephora* or *Daucus carota* have been demonstrated in the prior art. Thus, one of skill in the art would have been motivated to subject the callus cultures obtained from the plant species of *Theobroma cacao*, *Coffee canephora* or *Daucus carota* to cryopreservation protocols for the benefit of storing the plant materials. The use of a particular osmoticum concentration as well as the desiccation of plant material to a specific water content prior to cryopreservation is considered to be within the purview of the an ordinary skill

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practitioner. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

With regard to the claim rejection under 35 USC § 103 applicants' arguments are directed to unexpected results in increasing the rate of successful regeneration (page 5, last par.) However, it is uncertain as argued and as disclosed what is the plant material which has been included in or excluded from the claimed cryopreservation process. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova, Ph.D.

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July 31, 2002.


IRENE MARX
PRIMARY EXAMINER